

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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PAUL JOHNSON,

Plaintiff,

08 CV 0987 (BSJ)

v.

ANSWER & JURY DEMAND

ELI LILLY AND COMPANY,

Defendant.

-----X

Defendant Eli Lilly and Company ("Lilly"), by its attorneys, Pepper Hamilton LLP, answers the Complaint in this action as follows:

STATEMENT OF THE CASE

1. Lilly denies the allegations contained in Paragraph 1 of the Complaint, except admits that plaintiff purports to state a claim against Lilly.

PARTIES AND JURISDICTION

2. Lilly denies the allegations contained in Paragraph 2 (a-b) of the Complaint except admits that (i) subject matter jurisdiction exists pursuant to 28 U.S.C. § 1332, and (ii) at certain times, Lilly has been authorized to do business in the State of New York and in this judicial district.

3. Lilly denies the allegations contained in Paragraph 3 of the Complaint except admits that, at all times relevant to the Complaint Lilly was (and is) a corporation organized and existing under the laws of the State of Indiana, with its principal place of business in Indianapolis, Indiana.

4. Lilly denies the allegations contained in Paragraph 4 of the Complaint except admits that, at certain times, it has been authorized to do business in the State of New York.

5. Lilly denies the allegations contained in Paragraph 5 of the Complaint except admits that, at certain times, it has been authorized to do business in the State of New York.

6. Lilly denies the allegations contained in Paragraph 6 of the Complaint, except admits that, it has researched, tested, developed, manufactured, marketed and/or sold Zyprexa® to independent pharmaceutical wholesalers for use only upon prescription by a licensed physician in accordance with applicable laws and regulations, and for its approved indications with Food and Drug Administration (“FDA”) approved warnings regarding the risks and benefits of the medication.

7. Lilly denies the allegations contained in Paragraph 7 of the Complaint, except admits that, at relevant times, it researched, tested, developed, manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers for use only upon prescription by a licensed physician in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication.

8. Lilly denies the allegations contained in Paragraph 8 of the Complaint, except (i) admits that it researched, tested, developed, manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication, and (ii) admits that at certain times, Lilly has been authorized to do business in the State of New York.

9. Lilly denies the allegations contained in Paragraph 9 of the Complaint.

10. Lilly denies the allegations contained in Paragraph 10 of the Complaint.

11. Lilly denies the allegations contained in Paragraph 11 of the Complaint, except admits that at certain times, Lilly has been authorized to do business in the State of New York.

12. Lilly denies the allegations contained in Paragraph 12 of the Complaint, except admits that at certain times, Lilly has been authorized to do business in the State of New York.

BACKGROUND

NATURE OF THE CASE

13. Lilly denies the allegations contained in Paragraph 13 of the Complaint, except (i) admits that Zyprexa¹ is the brand name for olanzapine, (ii) admits that Lilly researched, tested, developed, manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with warnings approved by the FDA regarding the risks and benefits of the medication, and (iii) admits that Zyprexa is approved by the FDA for the treatment of schizophrenia, the treatment of acute mixed or manic episodes associated with Bipolar I Disorder and maintenance monotherapy, and the combination

¹ Although both Zyprexa and Zyprexa Zydis are administered orally, Zyprexa is a tablet formulation while Zyprexa Zydis is an orally disintegrating tablet formulation. For purposes of responding to the allegations in plaintiff's Complaint, Lilly avers that the only relevant distinction between Zyprexa and Zyprexa Zydis is that Lilly manufactures Zyprexa while Zyprexa Zydis is manufactured for Lilly by Cardinal Health, a successor to R.P. Scherer Corporation. Previously, Scherer DDS Ltd. manufactured Zyprexa Zydis for Lilly. Except where responding to those allegations in the Complaint relating to the manufacture of Zyprexa and Zyprexa Zydis, all references made by Lilly to Zyprexa are intended to address Zyprexa Zydis as well.

of Zyprexa with Lithium or Valproate is indicated for the short-term treatment of acute manic episodes associated with Bipolar I Disorder.

14. Lilly denies the allegations contained in Paragraph 14 of the Complaint.
15. Lilly denies the allegations contained in Paragraph 15 of the Complaint.
16. Lilly denies the allegations contained in Paragraph 16 of the Complaint.
17. Lilly denies the allegations contained in Paragraph 17 of the Complaint.
18. Lilly denies the allegations contained in Paragraph 18 of the Complaint.
19. Lilly denies the allegations contained in Paragraph 19 of the Complaint.

FACTUAL ALLEGATIONS

20. Lilly denies the allegations contained in Paragraph 20 of the Complaint, except admits that it researched, tested, developed, manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication.

21. Lilly denies the allegations contained in Paragraph 21 of the Complaint, except admits that on September 30, 1996, the FDA approved Zyprexa (olanzapine) for use in the management of manifestations of psychotic disorder.

22. Lilly denies the allegations contained in Paragraph 22 of the Complaint except admits that on March 17, 2000, the FDA approved Zyprexa for use in the “short-term treatment of acute manic episodes associated with Bipolar I Disorder.”

23. Lilly is without knowledge or information as to plaintiff’s meaning of the terms “third-best selling drug in the world” or “top selling drug” and therefore denies the allegations contained in Paragraph 23 of the Complaint, except Lilly admits that sales figures for Zyprexa are disclosed in its filings with the Securities and Exchange Commission (“SEC”),

which are publicly available, and denies any characterization or interpretation inconsistent with these documents when read in context and in their entirety.

24. Lilly denies the allegations contained in Paragraph 24 of the Complaint except admits that Zyprexa is a psychotropic agent that belongs in the thienobenzodiazepine class of medications also known as "atypical antipsychotics."

25. Lilly denies that the allegations contained in Paragraph 25 of the Complaint fully and accurately describe Zyprexa, and therefore denies the same as stated.

26. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the term "have available" and therefore denies the allegations contained in Paragraph 26 of the Complaint.

27. Lilly is without knowledge as to which "studies" plaintiff refers and therefore denies the allegations contained in Paragraph 27 of the Complaint.

28. Lilly denies the allegations contained in Paragraph 28 of the Complaint to the extent the allegations are inconsistent with findings and conclusions of the Duke University Study when read in context and in their entirety.

29. Lilly denies the allegations contained in Paragraph 29 of the Complaint to the extent that the allegations are inconsistent with any statements or warnings issued by the British Medicines Control Agency when read in context or in their entirety.

30. Lilly denies the allegations contained in Paragraph 30 of the Complaint to the extent that the allegations are inconsistent with any statements or warnings issued by the Japanese Health and Welfare Ministry when read in context or in their entirety.

31. Lilly denies the allegations contained in Paragraph 31 of the Complaint.

32. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of unidentified “pre-clinical studies” allegedly related to Zyprexa, and therefore denies the allegations contained in Paragraph 32 of the Complaint. By way of further response, to the extent that the averments in Paragraph 32 purport to refer to reports of unidentified studies, Lilly denies plaintiff’s description of the reports to the extent that it conflicts with such reports when read in context and in their entirety. Lilly further denies the allegations contained in Paragraph 32 of the Complaint regarding adverse event reports, except admits that applicable laws and regulations require the submission of adverse event reports to the FDA, and denies the allegations contained in Paragraph 32 of the Complaint to the extent the allegations are inconsistent with such reports when read in context and in their entirety. Lilly further denies the allegations contained in Paragraph 32 of the Complaint to the extent that the allegations are inconsistent with the statements contained in communications from the FDA, statements or warnings issued by the British Medicines Control Agency, and/or statements or warnings issued by the Japanese Health & Welfare Ministry when read in context and in their entirety, and denies all other allegations contained in Paragraph 32 of the Complaint.

33. Lilly denies the allegations contained in Paragraph 33 of the Complaint to the extent that the allegations are inconsistent with the statements contained in communications from the FDA to which plaintiff is referring when read in context and in their entirety.

34. Lilly denies the allegations contained in Paragraph 34 of the Complaint.

35. Lilly denies the allegations contained in Paragraph 35 of the Complaint as stated, except admits that information relating to certain Lilly products is disclosed in its filings with the SEC, which are publicly available, and denies any characterization or interpretation inconsistent with these documents when read in context and in their entirety.

36. Lilly denies the allegations contained in Paragraph 36 of the Complaint to the extent that the allegations are inconsistent with the statutes and regulations to which plaintiff is referring when read in context and in their entirety.

37. Lilly denies the allegations contained in Paragraph 37 of the Complaint.

38. Lilly is without knowledge as to plaintiff's meaning of the term "valid scientific evidence" and therefore denies the allegations contained in Paragraph 38 of the Complaint.

39. Lilly denies the allegations contained in Paragraph 39 of the Complaint.

40. Lilly denies the allegations contained in Paragraph 40 of the Complaint.

41. Lilly denies the allegations contained in Paragraph 41 of the Complaint.

42. Lilly denies the allegations contained in Paragraph 42 of the Complaint.

43. Lilly denies the allegations contained in Paragraph 43 of the Complaint.

44. Lilly denies the allegations contained in Paragraph 44 of the Complaint.

45. Lilly denies the allegations contained in Paragraph 45 of the Complaint.

46. Lilly denies the allegations contained in Paragraph 46 of the Complaint.

47. Lilly denies the allegations contained in Paragraph 47 of the Complaint.

48. Lilly denies the allegations contained in Paragraph 48 of the Complaint, except admits that it researched, tested, developed, manufactured, marketed, labeled, and/or sold Zyprexa to independent pharmaceutical wholesalers for use only upon prescription by a licensed physician, in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medications.

49. Lilly denies the allegations contained in Paragraph 49 of the Complaint.

50. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 50 of the Complaint.

51. Lilly denies the allegations contained in Paragraph 51 of the Complaint.

52. Lilly denies the allegations contained in Paragraph 52 of the Complaint.

53. Lilly denies the allegations contained in Paragraph 53 of the Complaint.

RESPONSE TO THE FIRST CAUSE OF ACTION AGAINST DEFENDANT

54. Lilly repeats and realleges with the same force and effect as if fully set forth here in full its answer to each and every allegation incorporated by reference in Paragraph 54 of the Complaint.

55. Lilly denies the allegations contained in Paragraph 55 of the Complaint, except admits that, at all times relevant to plaintiff's Complaint, it had a duty to exercise reasonable care in the research, testing, development, manufacturing, labeling, warning, marketing, and sale of Zyprexa. Lilly denies that it breached such a duty.

56. Lilly denies the allegations contained in Paragraph 56 of the Complaint.

57. Lilly denies the allegations contained in Paragraph 57 of the Complaint and each of its sub-parts.

58. Lilly denies the allegations contained in Paragraph 58 of the Complaint.

59. Lilly denies the allegations contained in Paragraph 59 of the Complaint and each of its sub-parts.

60. Lilly denies the allegations contained in Paragraph 60 of the Complaint.

61. Lilly denies the allegations contained in Paragraph 61 of the Complaint.

62. Lilly denies the allegations contained in Paragraph 62 of the Complaint.

63. Lilly denies the allegations contained in Paragraph 63 of the Complaint.

64. Lilly denies the allegations contained in Paragraph 64 of the Complaint.

65. Lilly denies the allegations contained in Paragraph 65 of the Complaint.

RESPONSE TO THE SECOND CAUSE OF ACTION AGAINST DEFENDANT

66. Lilly repeats and realleges with the same force and effect as if fully set forth here in full its answer to each and every allegation incorporated by reference in Paragraph 66 of the Complaint.

67. Lilly denies the allegations contained in Paragraph 67 of the Complaint, except is without knowledge or information to form a belief as to the truth or falsity of the allegations relating to the plaintiff, and admits that it researched, tested, developed, manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers for use only upon prescription by a licensed physician in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication.

68. Lilly denies the allegations contained in Paragraph 68 of the Complaint, except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 68 relating to "usual consumers, handlers, and persons coming into contact with said product."

69. Lilly denies the allegations contained in Paragraph 69 of the Complaint.

70. Lilly denies the allegations contained in Paragraph 70 of the Complaint.

71. Lilly denies the allegations contained in Paragraph 71 of the Complaint.

72. Lilly denies the allegations contained in Paragraph 72 of the Complaint.

73. Lilly denies the allegations contained in Paragraph 73 of the Complaint.

74. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 74 of the Complaint.

75. Lilly denies the allegations contained in Paragraph 75 of the Complaint.

76. Lilly denies the allegations contained in Paragraph 76 of the Complaint, except admits that, at all times relevant to plaintiff's Complaint, it had a duty to exercise reasonable care in the research, testing, development, manufacturing, labeling, warning, marketing, and sale of Zyprexa. Lilly denies that it breached such a duty.

77. Lilly denies the allegations contained in Paragraph 77 of the Complaint.

78. Lilly denies the allegations contained in Paragraph 78 of the Complaint.

79. Lilly denies the allegations contained in Paragraph 79 of the Complaint except is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 79 relating to the plaintiff.

80. Lilly denies the allegations contained in Paragraph 80 of the Complaint.

81. Lilly denies the allegations contained in Paragraph 81 of the Complaint.

82. Lilly denies the allegations contained in Paragraph 82 of the Complaint.

83. Lilly denies the allegations contained in Paragraph 83 of the Complaint.

84. Lilly denies the allegations contained in Paragraph 84 of the Complaint.

85. Lilly denies the allegations contained in Paragraph 85 of the Complaint.

86. Lilly denies the allegations contained in Paragraph 86 of the Complaint.

87. Lilly denies the allegations contained in Paragraph 87 of the Complaint.

88. Lilly denies the allegations contained in Paragraph 88 of the Complaint.

RESPONSE TO THE THIRD CAUSE OF ACTION AGAINST DEFENDANT

89. Lilly repeats and realleges with the same force and effect as if fully set forth here in full its answer to each and every allegation incorporated by reference in Paragraph 89 of the Complaint.

90. Lilly denies the allegations contained in Paragraph 90 of the Complaint.

91. Lilly denies the allegations contained in Paragraph 91 of the Complaint.

92. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 92 of the Complaint.

93. Lilly denies the allegations contained in Paragraph 93 of the Complaint.

94. Lilly denies the allegations contained in Paragraph 94 of the Complaint.

95. Lilly denies the allegations contained in Paragraph 95 of the Complaint.

96. Lilly denies the allegations contained in Paragraph 96 of the Complaint.

97. Lilly denies the allegations contained in Paragraph 97 of the Complaint.

98. Lilly denies the allegations contained in Paragraph 98 of the Complaint.

99. Lilly denies the allegations contained in Paragraph 99 of the Complaint.

100. Lilly denies the allegations contained in Paragraph 100 of the Complaint.

RESPONSE TO THE FOURTH CAUSE OF ACTION AGAINST DEFENDANT

101. Lilly repeats and realleges with the same force and effect as if fully set forth here in full its answer to each and every allegation incorporated by reference in Paragraph 101 of the Complaint.

102. Lilly denies the allegations contained in Paragraph 102 of the Complaint, except admits that it researched, tested, developed, manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers, for use only upon prescription by a licensed physician in accordance with applicable laws and regulations, and for its approved indications with FDA-approved warnings regarding the risks and benefits of the medication.

103. Lilly denies the allegations contained in Paragraph 103 of the Complaint, except admits that after receiving FDA approval to market Zyprexa, Lilly has marketed to physicians in accordance with applicable laws and regulations, with adequate communication of the known risks, and with adequate warnings commensurate with the risk and gravity of the possible side effects from its use.

104. Lilly denies the allegations contained in Paragraph 104 of the Complaint, except admits that it researched, tested, developed, manufactured, marketed, and/or sold Zyprexa to independent pharmaceutical wholesalers for use only upon prescription by a licensed physician in accordance with applicable laws and regulations, and for its approved warnings regarding the risks and benefits of the medication, and after receiving FDA approval to market Zyprexa, Lilly has marketed to physicians in accordance with applicable laws and regulations, with adequate communication of the known risks, and with adequate warnings commensurate with the risk and gravity of the possible side effects from its use.

105. Lilly denies the allegations contained in Paragraph 105 of the Complaint.

106. Lilly denies the allegations contained in Paragraph 106 of the Complaint, except admits that after receiving FDA approval to market Zyprexa, Lilly has marketed to physicians in accordance with applicable laws and regulations, with adequate communication of the known risks, and with adequate warnings commensurate with the risk and gravity of the possible side effects from its use.

107. Lilly denies the allegations contained in Paragraph 107 of the Complaint, except admits that after receiving FDA approval to market Zyprexa, Lilly has marketed to physicians in accordance with applicable laws and regulations, with adequate communication of the known risks, and with adequate warnings commensurate with the risk and gravity of the possible side effects from its use.

108. Lilly denies the allegations contained in Paragraph 108 of the Complaint.

109. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 109 of the Complaint.

110. Lilly is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 110 of the Complaint.

111. Lilly denies the allegations contained in Paragraph 111 of the Complaint.

112. Lilly denies the allegations contained in Paragraph 112 of the Complaint.

113. Lilly denies the allegations contained in Paragraph 113 of the Complaint.

114. Lilly denies the allegations contained in Paragraph 114 of the Complaint.

115. Lilly denies the allegations contained in Paragraph 115 of the Complaint.

116. Lilly denies the allegations contained in Paragraph 116 of the Complaint.

RESPONSE TO THE FIFTH CAUSE OF ACTION AGAINST DEFENDANT

117. Lilly repeats and realleges with the same force and effect as if fully set forth here in full its answer to each and every allegation incorporated by reference in Paragraph 117 of the Complaint.

118. Lilly denies the allegations contained in Paragraph 118 of the Complaint.

119. Lilly denies the allegations contained in Paragraph 119 of the Complaint.

120. Lilly denies the allegations contained in Paragraph 120 of the Complaint.

121. Lilly denies the allegations contained in Paragraph 121 of the Complaint.

122. Lilly denies the allegations contained in Paragraph 122 of the Complaint.

123. Lilly denies the allegations contained in Paragraph 123 of the Complaint.

124. Lilly denies the allegations contained in Paragraph 124 of the Complaint.

125. Lilly denies the allegations contained in Paragraph 125 of the Complaint.

126. Lilly denies the allegations contained in Paragraph 126 of the Complaint.

127. Lilly denies the allegations contained in Paragraph 127 of the Complaint.

128. Lilly denies the allegations contained in Paragraph 128 of the Complaint.

129. Lilly denies the allegations contained in Paragraph 129 of the Complaint.

RESPONSE TO THE SIXTH CAUSE OF ACTION AGAINST DEFENDANT

130. Lilly repeats and realleges with the same force and effect as if fully set forth here in full its answer to each and every allegation incorporated by reference in Paragraph 130 of the Complaint.

131. Lilly denies the allegations contained in Paragraph 131 of the Complaint.

132. Lilly denies the allegations contained in Paragraph 132 of the Complaint.

133. Lilly denies the allegations contained in Paragraph 133 of the Complaint and all of its sub-parts.

134. Lilly denies the allegations contained in Paragraph 134 of the Complaint and all of its sub-parts.

135. Lilly denies the allegations contained in Paragraph 135 of the Complaint, except admits that it had a duty to exercise reasonable care in the research, testing, development, manufacture, marketing, labeling, and sale of Zyprexa. Lilly denies that it breached such a duty.

136. Lilly denies the allegations contained in Paragraph 136 of the Complaint.

137. Lilly denies the allegations contained in Paragraph 137 of the Complaint.

138. Lilly denies the allegations contained in Paragraph 138 of the Complaint.

139. Lilly denies the allegations contained in Paragraph 139 of the Complaint.

140. Lilly denies the allegations contained in Paragraph 140 of the Complaint.

141. Lilly denies the allegations contained in Paragraph 141 of the Complaint.

142. Lilly denies the allegations contained in Paragraph 142 of the Complaint.

143. Lilly denies the allegations contained in Paragraph 143 of the Complaint.

RESPONSE TO THE SEVENTH CAUSE OF ACTION AGAINST DEFENDANT

144. Lilly repeats and realleges with the same force and effect as if fully set forth here in full its answer to each and every allegation incorporated by reference in Paragraph 144 of the Complaint.

145. Lilly denies the allegations contained in Paragraph 145 of the Complaint, except admits that it had a duty to exercise reasonable care in the research, testing, development, manufacture, marketing, labeling, and sale of Zyprexa. Lilly denies that it breached such a duty.

146. Lilly denies the allegations contained in Paragraph 146 of the Complaint, except admits that it had a duty to exercise reasonable care in the research, testing, development, manufacture, marketing, labeling, and sale of Zyprexa. Lilly denies that it breached such a duty.

147. Lilly denies the allegations contained in Paragraph 147 of the Complaint.

148. Lilly denies the allegations contained in Paragraph 148 of the Complaint.

149. Lilly denies the allegations contained in Paragraph 149 of the Complaint.

150. Lilly denies the allegations contained in Paragraph 150 of the Complaint.

151. Lilly denies the allegations contained in Paragraph 151 of the Complaint.

152. Lilly denies the allegations contained in Paragraph 152 of the Complaint.

153. Lilly denies the allegations contained in Paragraph 153 of the Complaint.

RESPONSE TO THE EIGHTH CAUSE OF ACTION AGAINST DEFENDANT

154. Lilly repeats and realleges with the same force and effect as if fully set forth here in full its answer to each and every allegation incorporated by reference in Paragraph 154 of the Complaint.

155. Lilly denies the allegations contained in Paragraph 155 of the Complaint.

156. Lilly denies the allegations contained in Paragraph 156 of the Complaint.

157. Lilly denies the allegations contained in Paragraph 157 of the Complaint.

FIRST AFFIRMATIVE DEFENSE

1. The Complaint fails to state a claim upon which relief can be granted against Lilly.

SECOND AFFIRMATIVE DEFENSE

2. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations.

THIRD AFFIRMATIVE DEFENSE

3. Venue is improper in this judicial district.

FOURTH AFFIRMATIVE DEFENSE

4. Some or all of plaintiff's claims are barred by the learned intermediary and/or sophisticated user doctrines. At all relevant times herein, plaintiff's prescribing physicians were in the position of sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of Zyprexa.

FIFTH AFFIRMATIVE DEFENSE

5. The injuries, damages, and losses alleged in the Complaint, none being admitted, were caused in whole or in part by the negligence of the plaintiff and/or others, over whom Lilly exercised no control, had no opportunity to anticipate or right to control, and with whom Lilly had no legal relationship by which liability could be attributed to it because of the actions of the plaintiff and/or others, which by comparison was far greater than any conduct alleged as to Lilly.

SIXTH AFFIRMATIVE DEFENSE

6. Plaintiff's alleged loss, damage, injury, harm, expense, diminution, or deprivation alleged, if any, was caused in whole or in part by plaintiff's failure to exercise reasonable care and diligence to mitigate their alleged damages.

SEVENTH AFFIRMATIVE DEFENSE

7. Plaintiff's claims are preempted by federal law in that Zyprexa was researched, tested, developed, manufactured, labeled, marketed and sold in a manner consistent with the state of the art at the pertinent time and approved by the FDA.

EIGHTH AFFIRMATIVE DEFENSE

8. Some or all of plaintiff's claims are barred by the doctrines concerning unavoidably unsafe products, including, but not limited to, the operation of comments j and k to Section 402A of the Restatement (Second) of Torts and/or barred by the Restatement (Third) of Torts.

NINTH AFFIRMATIVE DEFENSE

9. Plaintiff's claims are barred in whole or in part by the applicable provisions of the United States Constitution, the New York Constitution and/or the applicable Constitution of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. These provisions include, but are not limited to, the First Amendment to the Constitution of the United States and/or Article 1, § 8 of the New York Constitution because Lilly's commercial speech regarding Zyprexa was neither false nor misleading.

TENTH AFFIRMATIVE DEFENSE

10. Lilly alleges that plaintiff was fully informed of the risks of the use of the product made the subject of this action by the treating physicians, and the informed consent given by plaintiff is pleaded as an affirmative defense.

ELEVENTH AFFIRMATIVE DEFENSE

11. Plaintiff's claim for punitive damages violates, and it is therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America on grounds including the following:

- a. It is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiff satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;
- b. Procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;
- c. The procedures pursuant to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- d. The procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- e. The procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;
- f. The procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and

Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

g. The procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

h. The award of punitive damages to plaintiff in this action would constitute a deprivation of property without due process of law; and

i. The procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

TWELFTH AFFIRMATIVE DEFENSE

12. With respect to plaintiff's demand for punitive or exemplary damages, Lilly specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damages awards, including but not limited to, those standards of limitation which arose in *BMW of North America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003); and *Philip Morris USA v. Williams*, 127 S. Ct. 1057 (2007).

THIRTEENTH AFFIRMATIVE DEFENSE

13. Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction, in that FDA is charged under the law with regulating prescription drugs, including Zyprexa, and is specifically charged with determining the content of the warnings and labeling for prescription drugs. The granting of the relief prayed for in the plaintiff's Complaint would impede, impair, frustrate or burden the

effectiveness of such federal law and would violate the Supremacy Clause (Art. VI, cl. 2) of the United States Constitution.

FOURTEENTH AFFIRMATIVE DEFENSE

14. To the extent plaintiff's claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

FIFTEENTH AFFIRMATIVE DEFENSE

15. The injuries or damages allegedly sustained by plaintiff can be attributed to several causes and accordingly should be apportioned among the various causes according to respective contribution of each such cause to the harm sustained, if any. If any liability is found against Lilly, then said liability will constitute 50% or less of the total liability assigned to all persons liable, and as such, the liability of Lilly to plaintiff for non-economic loss shall be limited, and shall not exceed Lilly's equitable share.

SIXTEENTH AFFIRMATIVE DEFENSE

16. Any verdict or judgment rendered against Lilly must be reduced by those amounts that have been, or will, with reasonable certainty, replace or indemnify plaintiff, in whole or in part, for any past or future claimed economic loss, from any collateral source such as insurance, social security, workers' compensation or employee benefit programs.

SEVENTEENTH AFFIRMATIVE DEFENSE

17. Plaintiff's breach of warranty claims are barred because there is no privity of contract between the plaintiff and Lilly; plaintiff failed to give timely notice of any alleged breach of warranty to Lilly; plaintiff did not reasonably rely upon any alleged warranty; plaintiff failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty; and the warranty was appropriately disclaimed, excluded or modified.

EIGHTEENTH AFFIRMATIVE DEFENSE

18. Upon information and belief, some or all of the injuries alleged in the Complaint were caused by preexisting medical conditions, subsequent medical conditions, and the natural course of those conditions of the plaintiff, by an idiosyncratic reaction, operation of nature, or act of God, for which Lilly is not responsible.

NINETEENTH AFFIRMATIVE DEFENSE

19. One or more of Plaintiff's claims are barred by the doctrine of release. Lilly hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves the right to amend this list to assert such defenses.

WHEREFORE, defendant Eli Lilly and Company requests that plaintiff's Complaint, and all claims alleged therein, be dismissed with prejudice, that Lilly be awarded the costs, disbursements, and attorneys' fees in the defense of this action, and that Lilly be granted any other relief to which it may be entitled.

Dated: New York, New York
April 8, 2008

PEPPER HAMILTON LLP

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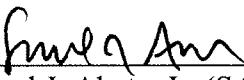
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Eli Lilly and Company

JURY DEMAND

Lilly demands a trial by jury on all issues triable in this action.



Samuel J. Abate, Jr. (SA 0915)